

JAN 24 1997

K964576

## Non-Confidential Summary of Safety and Effectiveness

page 1 of 3

November 4, 1996

Nellcor Puritan-Bennett, Inc.  
10200 Valley View Rd.  
Eden Prairie, MN 55344

Tel - (612) 941-3006

Fax - (612) 829-5423

**Official Contact:** Chris Hadland, Director, RA and QA  
**Proprietary or Trade Name:** TAP  
**Common/Usual Name:** Oral Appliance - anti-snoring device  
**Classification Name:** Anti-snoring device  
**Device:** TAP  
**Predicate Devices:** SnoreFree - OSAP - K960673  
Distar, Inc. - TheraSnore - K926382  
Dental Services group - Adjustable PM Positioner - K#  
unknown

### Device Description:

The TAP anti-snoring device is comprised of -

- \* Lower tray fitted over the lower teeth.
- \* Upper tray fitted over the upper teeth.
- \* Impression material
- \* Hook mechanism to attach lower tray to upper tray

### Intended Use:

**Indicated Use --** The TAP is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea, OSA.

**Target population - -** Adult patients

**Environment of Use - -** Home and sleep laboratories

# Non-Confidential Summary of Safety and Effectiveness (continued)

page 2 of 3

November 4, 1996

## Comparison to Predicate Devices:

Attribute	TAP K962516	OSAP K960673	PM Positioner Unknown	TheraSnore K92638
-----------	----------------	-----------------	--------------------------	----------------------

## Use

Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes	Yes	Yes
Indicated for use with patients with mild to moderate OSA	Yes	Yes	Yes	Yes
Indicated for single patient multi - use	Yes	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes	Yes

## Design

Rigid tray pieces	Yes	Yes	Yes	Yes
Heat sensitive impermissible material for fitting to teeth	Yes	Yes	Yes	Yes
Separate tray pieces	Yes	No	No	No
Custom fit for each patient	Yes	Yes	Yes	Yes
Works by holding lower jaw forward	Yes	Yes	Yes	Yes
Can be adjusted or refit	Yes	No	Yes	Yes
Placed in patient mouth each evening	Yes	Yes	Yes	Yes
Cleaned daily	Yes	Yes	Yes	Yes
Permits lateral and / or vertical jaw movement	Yes	No	No	No

# Non-Confidential Summary of Safety and Effectiveness (continued)

page 3 of 3

November 4, 1996

## Comparison to Predicate Devices: (continued)

Attribute	TAP K962516	OSAP K960673	PM Positioner Unknown	TheraSnore K926382
-----------	----------------	-----------------	--------------------------	-----------------------

## Design (continued)

Upper and lower tray unhook for easy removal from mouth	Yes	No	No	No
Permits patient to talk and drink with appliance in place	Yes	No	No	No
Permits patient to breath through mouth	Yes	No	No	No

## Materials

Rigid tray material	Yes	Yes	Yes	Yes
Heat sensitive impression material	Yes	Yes	Yes	Yes

## Performance Testing

None applicable under Section 514	Yes	Yes	Yes	Yes
reduced AHI in patients	72%	Yes	Yes	Yes
AHI performance comparable to CPAP	Yes	Yes	Unknown	Unknown

## Differences Between Other Legally Marketed Predicate Devices

The difference between the intended device and predicates is that the intended device is a 2 piece construction. This difference does not have a significant effect on the safety or effectiveness of the device.